COMPACT SUTURE PUNCH WITH MALLEABLE NEEDLE

Reference to Related Application

This application is a continuation-in-part application of U.S. Patent Application Serial No. 10/165,468, filed June 7, 2002, which claims priority to U.S. Provisional Patent Application Serial No. 60/310,220, filed August 6, 2001.

Field of the Invention

This invention relates generally to surgical suturing and, in particular, to improved articles, instrumentation, and methods therefore.

Background of the Invention

Suture passing is problematic for the arthroscopic surgeon because the braided suture preferred by most arthroscopists cannot be pushed through a cannulated instrument. Braided suture must be pulled into location because applying a push force causes the braid to expand in diameter, thereby wedging in the instrument.

Various solutions have been devised for passing braided suture. The Caspari Suture Punch (Linvatec Corporation, Largo, Florida) has been a very useful arthroscopic suture-passing instrument. Tissues may be approached head on, grasped and punctured with a cannulated needle, then monofilament suture wheeled through the tissue. A doubled monofilament may be used as a shuttle to pass another braided suture or, alternatively, a Linvatec Suture Shuttle may be wheeled through a slotted Caspari Suture Punch and used to shuttle suture. Surgical Dynamics has a similar device that shuttles a needle from one side of the punch to the other, passing the needle and attached thread through tissue.

The Caspari suturing instrument, described in U.S. Patent Nos. 4,890,615, 4,923,461 and 4,957,498, includes a hollow needle for penetrating tissue to be sutured within the body while the tissue is clamped between relatively movable jaws, and a suture feed mechanism for feeding suture material through the hollow needle such that the jaws may be opened and the suturing instrument withdrawn from the body pulling the free end segment of the suture

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material with the instrument. A knot may be tied in the suture material externally of the body and the knot moved back into the body at a position adjacent the tissue.

U.S. Patent No. 5,254,126 discloses an endoscopic suture punch for use in endosurgical procedures having an elongate frame and a handle mounted to one end of the frame. A pair of opposed jaws having tissue punches is mounted to the other end of the frame. One jaw is rigidly mounted to the frame while the other jaw is movably mounted to the frame, although both jaws may be movably mounted. An actuation handle is mounted to the frame for actuating the jaws. The suture punch has a suture pathway through the frame, the punches and the jaws for receiving the suture. There is a suture drive mechanism mounted to the frame for moving the suture through the suture pathway.

The surgical suturing apparatus described in U.S. Patent No. 5,454,823 comprises upper and lower jaw elements selectively movable relative to one another between open and closed position. Each jaw element is provided with a respective recess arranged to receive a portion of an elongate incision member or length of surgical thread and securing means is provided arranged to selectively secure the surgical incision member or length of surgical thread in a respective recess. The jaw elements are typically provided at an end of an elongate positioning and operating arm making the device particularly useful for use in laparoscopic surgery.

More recently, U.S. Patent No. 6,051,006 describes a suture-passing forceps having a first jaw with a mount which supports a needled suture and a second jaw having a passage, which when aligned with the mount, is positioned to receive the needled suture. The second jaw is positioned relative to the mount in a manner which allows delivery of the instrument to a surgical site in a low profile, delivery position (e.g., with the jaws spaced relatively closely). The surgical instrument includes an elongated shaft having a distal region for supporting the jaws. The second jaw is pivotable, with respect to the mount, between the delivery position in which the second jaw is spaced relatively closely to the mount with the passage misaligned with the mount and an open, misaligned position, the second jaw being axially translatable relative to the mount to an open, aligned position in which the passage is aligned with the mount.

A shortcoming of these and other such devices is the lack of room available to open the jaws sufficiently in tight spaces (a clearance issue), difficulty in forcing the tooth through the full thickness of the tissue (the tip gradually dulls and some tissue like the rotator cuff is just too thick) and fairly large diameter cannulas are required for passage.

Other "blitzes" and similar devices also have rather large diameter cannulated needles that pierce the tissue then deploy a loop or other mechanism to transport suture through the tissue. These are cumbersome to use, often requiring skillful rotation and pushing of the device by the surgeon to accomplish the selected result. Additionally, some concern exists with regard to the size of the hole placed in the tissue and the amount of damage requiring repair. This is especially true of the newer "Arthropierce" instrument currently in use.

Common to existing devices is a body capable undergoing elastic deformation during use but which retains a preformed shape when in an unconstrained condition. Of particular usefulness in these devices is Nitinol, a so-called "shape retention" alloy having an extremely high yield point. Nitinol components are formed during manufacture to a selected shape, and will return to this shape when in an unconstrained condition even after undergoing significant deformation. Preformed Nitinol needles and shuttles may be passed through cannulated instruments and will return to their original shapes when in an unconstrained state. This allows shuttle loops to be passed through cannulated instruments without permanent deformation. All Nitinol components may be formed to their selected shapes during manufacture.

As an example of an invention utilizing this effect, U.S. Patent No. 5,607,435 describes a medical instrument including a tubular section having a leading end terminating in a sharp point and a surgical needle exhibiting "superelastic characteristics." As such, the needle may remain straight as it is inserted through the delivery tube without developing substantial permanent deformation. While in the delivery tube and in this substantially straight condition, the needle is delivered to the suturing site. Once at the suture site, the surgical needle is extended out of the leading end of the delivery tube, returning it to its original curved or bent shape for suturing. A suture thread or wire is operatively disposed in the bore of the tubular section with one end extending out the tip through a slot so as to

remain in position to form a suture upon removal of the tubular needle from tissue. A tweezers instrument may then be used to grip and tie the thread into a suture knot.

Similarly, U.S. Patent No. 5,749,879 discloses a cannulated instrument for use in conjunction with "an elastic needle." In the preferred embodiment, the needle is of a pseudoelastic shape memory alloy and has an arced shape while the needle's alloy is in a substantially austenitic phase, and the needle may be stressed into a more straight shape in which the needle's alloy enters an at least partially more martensitic phase. When the needle is held entirely within the cannula, the needle is straightened and contains more stress-induced-martensite phase. As the needle is extruded from the distal end portion of the cannula, that portion of the needle which extends beyond the cannula returns toward its original shape by a martensitic-to-austenitic shape memory phase change caused by at least partial relief of the stress-induced-martensite in the needle's alloy. A cannula insert includes a longitudinal bore which may be used to contain a suture attached to the needle. Suitably, the bore may extend longitudinally entirely through the cannula insert, to permit an unlimited length of suture to be pulled therethrough.

Despite these advances, the need remains for a suture punch capable of passing braided suture without the use of a shuttle or similar means. Beneficially, such an instrument would be capable of passing suture while not requiring multiple or complex sequential operations or a high level of surgeon skill. In other embodiments, it would also be beneficial that the suture punch pass through a small diameter (i.e., 8 mm or less) cannula, and that the hole created in the tissue for passage of the suture be as small as possible.

Summary of the Invention

This invention overcomes deficiencies in the prior art by providing a suture punch system capable of directly passing suture material, such as braided suture material, through tissue in a simple, one-step process. The system includes three principle components: a malleable needle capable of delivering the suture material to the tissue, a handheld instrument for grasping tissue and controlling needle placement, and a trocar or other mechanism to supply the force required for needle formation and placement.

The needle differs from standard needles in terms of size, shape and material properties. In beneficial embodiments, the needle is shorter than standard needles, generally 10 to 13 mm in length, and has a cross-section which may be circular or non-circular, including rectangular with at least two parallel sides. The rectangular needles may have varying thicknesses and have a cross-section that ranges from substantially square to substantially flat. Additionally, the needle is made of a malleable material permitting it to be shaped within the handheld instrument and to retain its form while passing through tissue. The needle may also return to its form after passing through the tissue or once any bending force has been removed. Similarly, the distal portion of the trocar may be malleable, thereby permitting shaping within the handheld instrument.

In contrast to existing suture punches in which the needle or shuttle undergoes only an elastic deformation during use and the functional un-constrained shape of the needle or shuttle is produced during manufacture, the needle of the disclosed device may be inelastically formed to its functional shape during use, allowing the needle to traverse a nonlinear path. More particularly, when passing through the distal tip of the hand instrument, the needle may be inelastically formed by a radial path within the instrument, the plane of the radius being substantially unparallel to the tissue through which the suture is being passed. The formation of this radius is facilitated by the aforementioned parallel sides of the needle cross-section which are constrained by the instrument in such a manner as to place them essentially in the plane of the tissue.

Needle deformation begins as the tip of the needle passes through the radius within the instrument and continues as the needle is forced distally by a force-supplying mechanism. As the distal tip of the needle pierces the tissue, it continues its radial path through the tissue, the radius of the path being determined by the unconstrained radius of the needle. This unconstrained radius may be larger than that of the forming radius within the instrument due to "spring back" of the needle, the degree of which is determined by the material properties of the needle, its cross section, and features formed in the parallel surfaces of the needle during manufacture.

Forming of the needle along its length continues as it is passes from the distal tip of the instrument into the tissue. When the proximal end of the needle exits from the instrument, the needle may be entirely radial in shape and traverse an essentially radial path through the tissue. Due to the degree of spring back, the needle, in certain embodiments, may also return to its non-deformed shape. As used herein, the term "spring back" is meant to define the degree of elasticity of the malleable needle after it has exited the instrument. A "spring back" of 100 percent would apply to a needle that returns to its original shape whereas a needle having a "spring back" of 0 percent would maintain the shape of the curved segment of the instrument after the needle has exited the instrument. The present invention may use needles having a degree of spring back of from 0 to 100 percent. In select embodiments, wherein an inelastic material is used, the needle has a spring back of from 0 to about 10 percent. In alternative embodiments, wherein an elastic material is used, the needle has a spring back of from about 90 to about 100 percent.

After the proximal end of the needle exits the instrument, the needle may be propelled further along its radial path by the force-supplying mechanism, such as a trocar. Additionally, the distal portion of the mechanism may be formed to a radial shape by the instrument in the same manner as the needle. Additionally, the radial shapes of the needle and mechanism may also be coplanar. Engagement of the mechanism with the needle after the needle passes from the instrument may be facilitated by mating surfaces of the mechanism and needle, shaped, for example, to prevent radial or lateral displacement of the needle proximal and mechanism distal surfaces. The mechanism may also be engaged with the needle in a manner that connects the mechanism and needle together such that the connection is capable of being broken after the needle has exited the instrument.

The passage in the instrument within which the needle travels, and the forming radius in the instrument distal tip, each comprise open-sided channels allowing the suture carried by the needle to travel unimpeded during its forming and insertion into the tissue. As the force-supplying mechanism pushes the needle further into the tissue, the suture is carried along by the needle through the passage formed in the tissue to deliver the suture to the tissue.

During use, the tissue to be sutured is constrained by pressure applied through closure between the upper, moveable jaw of the instrument and the distal portion of the instrument which acts as a fixed jaw. The upper, movable jaw contains a shaped passageway that allows the curved needle to pass therethrough during use. After the force-supplying mechanism has been fully inserted into the instrument and the needle has achieved maximum travel into the tissue, the mechanism may be withdrawn from the instrument.

When suturing thin sections, the needle may be passed completely through the tissue and may then be ready for retrieval using the jaws of the punch or another instrument. In the case of thick tissue, 70 percent or more of the needle may protrude from the tissue after the force-supplying mechanism is fully inserted, such that opening the upper jaw slightly and moving the instrument in a proximal direction would cause the needle to wedge in the upper jaw passage, permitting the needle to be withdrawn completely from the tissue. Following this procedure, the needle may be retrieved using the punch or another instrument.

Accordingly, in one embodiment, the present invention provides suturing instrumentation for suturing tissue having a malleable needle portion having a sharpened distal tip and constructed and arranged to deliver a length of suture material to the tissue; a handheld instrument having a passageway and having a distal end terminating in a nonlinear portion having a first radius; and a force-supplying structure for applying a force to the needle portion, wherein the force-supplying structure includes a distal end capable of pushing the malleable needle portion through the nonlinear portion, such that when the distal end of the handheld instrument is positioned proximate to the tissue to be sutured and the malleable needle portion is pushed by the distal end of the force-supplying structure through the nonlinear portion, the needle portion is deformed, thereby causing the needle portion to deliver the suture material to the tissue.

In another embodiment, the present invention provides suturing instrumentation for suturing tissue having a malleable needle portion having a sharpened distal tip and constructed and arranged to deliver a length of suture material to the tissue; a handheld instrument having a passageway and having a distal end terminating in a nonlinear portion having a first radius; and a force-supplying structure for applying a force to the needle

portion, wherein the force-supplying structure includes a distal end capable of pushing the malleable needle portion through the nonlinear portion, such that when the distal end of the handheld instrument is positioned proximate to the tissue to be sutured and the malleable needle portion is pushed by the distal end of the force-supplying structure through the nonlinear portion, the needle portion is deformed, thereby causing the needle portion to deliver the suture material to the tissue; and a jaw pivotally coupled to the distal end of the handheld instrument for holding tissue as the needle portion and suture material enters into the tissue.

In yet another embodiment, the present invention provides a suture needle adapted for use with a handheld instrument defining an axis and having an off-axis distal end, the needle including a length of material having a sharpened distal tip and constructed and arranged to deliver a length of suture material; and the material of the needle being malleable, such that when the needle is pushed through the handheld instrument, it elastically deforms in accordance with the off-axis distal end.

In still another embodiment, the present invention provides a suturing system having a malleable needle portion having a sharpened distal tip and constructed and arranged to deliver a length of suture material; a handheld instrument having a passageway and having a distal end terminating in a nonlinear portion; and a push member configured for movement in the passageway of the handheld instrument, the push member being operative to push the malleable needle portion through the nonlinear portion, such that when the distal end of the handheld instrument is positioned proximate to a tissue to be sutured and the needle portion is pushed by the push member through the nonlinear portion, the needle portion is deformed and enters into the tissue and delivers the suture material to the tissue being sutured.

In yet another embodiment, the present invention provides a method for suturing, including the steps of providing a malleable needle portion having a sharpened distal tip; positioning the needle in a passageway of a handheld instrument; providing a suture material to be delivered by the needle portion; and using a push member to push the needle portion in the handheld instrument, the needle portion upon exiting the handheld instrument penetrating the tissue being sutured and delivering the suture material to the tissue being sutured.

In still another embodiment, the present invention provides a system and method for suturing using a smaller suture wherein the needle is designed such that the suture may be looped back directly into the needle. As such, when the push member pushes the needle portion into and/or through the tissue, the needle delivers a loop of suture material that may then be used as an eyelet or other mechanism for the transfer of other suture. Alternatively, a smaller needle may be used during delivery of the suture to create a loop of suture material in the tissue to be sutured.

Brief Description of the Drawings

FIGURE 1 is a plan view of a suture punch formed in accordance with the principles of this invention;

FIGURE 2 is a side view of the instrument of Figure 1;

FIGURE 3 is an end view of the instrument of Figure 1;

FIGURE 4 is an expanded view of the distal tip of the instrument of Figure 1;

FIGURE 5 is a sectional view of the distal tip of Figure 2 at location A – A;

FIGURE 6 is a sectional view of the distal tip of Figure 2 at location B – B;

FIGURE 7 is a sectional view of the instrument at location C – C;

FIGURE 8 is a sectional view of the instrument at location D – D;

FIGURE 9 is a sectional view of the instrument at location E – E with the trocar and needle removed;

FIGURE 10 is an expanded view of the distal tip of the instrument;

FIGURE 11 is a plan view of a needle constructed in accordance with the principles of this invention;

FIGURE 12 is a side view of the needle of Figure 5;

FIGURE 13 is an end view of the needle of Figure 5;

FIGURE 14 is a plan view of the upper jaw of the instrument;

FIGURE 15 is a side view of the upper jaw of Figure 14;

FIGURE 16 is a sectional view of the upper jaw of Figure 14;

FIGURE 17 is an end view of the upper jaw of Figure 14;

FIGURE 18 is a trocar used in accordance with one embodiment of this invention;

FIGURE 19 is an expanded view of the distal end of the trocar of Figure 18;

FIGURE 20 is an expanded sectional view of the proximal end of the trocar of Figure 18;

FIGURE 21 is an expanded view of the distal portion of the trocar of Figure 19;

FIGURE 22 is an end view of the trocar of Figure 18;

FIGURE 23 is a sectional view of the instrument of Figure 1 with trocar and needle in place;

FIGURE 24 is an expanded view of the distal portion of Figure 23;

FIGURE 25 shows a needle and trocar loaded and the upper jaw open in preparation for use;

FIGURE 26 is an expanded view of the distal end of the instrument of Figure 25;

FIGURE 27 depicts the instrument grasping tissue in preparation for passing a needle with suture therethrough;

FIGURE 28 is an expanded view of the distal end of the instrument grasping tissue as shown in Figure 27;

FIGURE 29 shows the trocar now advanced so that the needle tip is beginning to pierce tissue grasped between the instrument jaws;

FIGURE 30 is an expanded view of the distal end of the instrument shown in Figure 29;

FIGURE 31 shows the trocar advanced so that the needle has approximately 90 percent penetration of tissue grasped between the instrument jaws;

FIGURE 32 is an expanded view of the distal end of the instrument shown in FIGURE 31;

FIGURE 33 shows the trocar advanced so that the needle has passed through tissue grasped between the instrument jaws and protrudes beyond the superior surface of the moveable jaw;

FIGURE 34 is an expanded view of the distal end of the instrument of Figure 33;

FIGURE 35 shows the trocar fully advanced so that the trocar distal tip has forced the needle proximal end significantly through the tissue grasped between the instrument jaws;

FIGURE 36 is an expanded view of the distal end of the instrument of Figure 35;

FIGURE 37 is similar to Figure 35, but with the trocar retracted so that only the needle and suture remain within the tissue;

FIGURE 38 is an expanded view of the distal end of the device of Figure 37;

FIGURE 39 is similar to Figure 37, but with the moveable jaw retracted;

FIGURE 40 is an expanded view of the distal end of Figure 39;

FIGURE 41 is similar to Figure 30, but with the distal end retracted proximally from the tissue so that the needle is pulled from the tissue by the moveable jaw;

FIGURE 42 is an expanded view of the distal end of Figure 41;

FIGURE 43 is similar to Figure 41, but with the needle grasped between the jaws of the instrument;

FIGURE 44 is an expanded view of the distal end of Figure 43;

FIGURE 45 is similar to Figure 43, but with the needle rotated and grasped between the jaws in preparation for withdrawal through the cannula;

FIGURE 46 is an expanded view of the distal end of Figure 45;

FIGURE 47 is a plan view of an alternate needle configuration according to the invention;

FIGURE 47a is a plan view of an alternate suture configuration according to one embodiment of the invention;

FIGURE 48 is a side view of the needle configuration of Figure 47;

FIGURE 49 is an end view of the needle configuration of Figure 47;

FIGURE 50 is a plan view of yet a further alternate needle configuration according to the invention;

FIGURE 51 is a side view of the alternate needle configuration of Figure 50;

FIGURE 52 is an end view of the alternate needle configuration of Figure 50;

FIGURE 53 is a plan view of an alternate top jaw configuration according to the invention;

FIGURE 54 is a side view of the alternate top jaw configuration of Figure 53;

FIGURE 55 is an end view of the alternate top jaw configuration of Figure 53;

FIGURE 56 is a sectional view of the alternate top jaw configuration of Figure 53;

FIGURE 57 is a sectional view of upper and lower jaws with jaws closed and needle fully extended;

FIGURE 58 is a sectional view of upper and lower jaws with jaws opened 50 percent and needle fully extended;

FIGURE 59 is a sectional view of upper and lower jaws with jaws opened 100 percent and needle fully extended;

FIGURE 60 is a sectional view of upper and lower jaws with jaws opened 100 percent and the suture being pulled through the tissue;

FIGURE 61 is a plan view of yet a different alternate needle according to the invention;

FIGURE 62 is a lateral side view of the different alternate needle of Figure 61;

FIGURE 63 is an end-on view of the alternate needle of Figure 61 viewed from the distal tip;

FIGURE 64 is a plan view of an alternate construction of the upper/moveable jaw;

FIGURE 65 is a side view of the alternate construction of the upper/moveable jaw of FIGURE 64;

FIGURE 66 is a bottom-side plan view of the alternate construction of the upper/moveable jaw of Figure 64;

FIGURE 67 is an end view of the alternate construction of the upper/moveable jaw of FIGURE 64 from the proximal end;

FIGURE 68 is an end view of the alternate construction of the upper/moveable jaw of FIGURE 64 from the distal tip;

FIGURE 69 is a sectional view of the alternate construction of the upper/moveable jaw of Figure 64 in direction J – J;

FIGURE 70 Is a sectional view of the alternate construction of the upper/moveable jaw of Figure 64 in direction K – K;

FIGURE 71 is a sectional view of the alternate construction of the upper/moveable jaw of Figure 64 in direction L – L;

FIGURE 72 is a sectional view of the upper jaw of Figure 64 assembled to the lower jaw and with the needle of Figure 61 deployed in tissue and ready for retrieval;

FIGURE 73 is a sectional view of the upper jaw of Figure 64 assembled to the lower jaw and with the needle of Figure 61 captured in the upper jaw;

FIGURE 74 is a sectional view of the upper jaw of Figure 64 assembled to the lower jaw and with the needle of Figure 61 captured in the upper jaw and withdrawn from the tissue;

FIGURE 75 is a sectional view of the upper jaw of Figure 64 assembled to the lower jaw and with the needle of Figure 61 captured by the instrument and positioned for withdrawal through a cannula;

FIGURE 76 is an alternate needle having a radial shape and made of Nitinol;

FIGURE 77 is a plan view of the needle of Figure 76 prior to forming;

FIGURE 78 is an end view of the needle of Figure 76;

FIGURE 79 is a plan view of an alternate needle according to the invention;

FIGURE 80 is a side view of the needle of Figure 79;

FIGURE 81 is an end view of the needle of Figure 79;

FIGURE 82 is a plan view of an alternate top jaw according to the invention;

FIGURE 83 is a side view of the alternate top jaw of Figure 82;

FIGURE 84 is a side sectional view of the alternate top jaw of Figure 82;

FIGURE 85 is an end view of the alternate top jaw of Figure 82;

FIGURE 86 is an expanded lateral sectional view of the alternate top jaw of Figure 82;

FIGURE 87 is a drawing of a jawless suture punch according to the present invention;

FIGURE 88 is a drawing of a trocar pusher adapted for use with the jawless punch of Figure 87;

FIGURE 89 is a drawing of the distal tip of an angled jaw or jaw-less design according to the present invention;

FIGURE 90 is a drawing of a particularized capsular plication suture punch for the shoulder according to the present invention;

FIGURE 91 is a simplified drawing which shows the way in which three rigidly positioned points may be used to curve a needle into a selected radius according to the present invention;

FIGURE 92 is a drawing depicted in partial transparent form, illustrating a more sophisticated jawless punch according to the present invention;

FIGURE 93 is an oblique view of the device of Figure 92;

FIGURE 94 is a close-up view of the distal end including the curved tip;

FIGURE 95 is a side-view of the device of Figure 93 with the needle loaded in position;

FIGURE 96 is a perspective-view of the configuration shown in Figure 95;

FIGURE 97 is a side-view showing the trocar being advanced by pushing on the proximal end of the pusher rods;

FIGURE 98 shows the needle being pushed passed the breached loading position, with the suture material extending out from a slot;

FIGURE 99 shows the needle being deformed and pushed out the distal end;

FIGURE 100 shows the needle fully advanced, now free of the distal tip of the instrument;

FIGURE 101 is a close-up, detail view of the needle emerging from the curved distal tip of the instrument;

FIGURE 102A shows the jaws open ready to grab the tip of the needle;

FIGURE 102B shows the needle grasped;

FIGURE 102C shows how, even once grasped, the tip of the needle may rotate within the jaws;

FIGURES 103A-103C are side views of the embodiments of Figures 102A-102C;

FIGURE 104 is a perspective view of the grasping mechanism in conjunction with the tip of the needle;

FIGURE 105A is a first view of a needle according to the invention particularly suited to certain shoulder procedures;

FIGURE 105B is a different view of the needle of Figure 105A;

FIGURE 105C is a end-on view of the needle of the Figures 105A and 105B;

FIGURE 106 is a retrieval instrument associated with the needle of Figure 105;

FIGURE 107A is a close-up view drawing of the retrieval tip of the instrument of Figure 106;

FIGURE 107B is a different view of the retrieval tip;

FIGURE 107C is an end-on view of the retrieval tip;

FIGURE 108 shows a distal portion of an insertion instrument; and

FIGURE 109A through 109K show the way in which the needle of Figure 105, insertion of Figure 108 and retrieval instrument of Figures 106 and 109 are used.

Detailed Description of the Invention

The present invention is more particularly described in the following examples that are intended to be illustrative only since numerous modifications and variations therein will be apparent to those skilled in the art. As used in the specification and in the claims, the singular form "a," "an," and "the" may include plural referents unless the context clearly dictates otherwise. Also, as used in the specification and in the claims, the term "comprising" may include the embodiments "consisting of" and "consisting essentially of."

The present invention will now be further described through the following drawings. It is to be understood that these drawings are non-limiting and are presented to provide a better understanding of various embodiments of the present invention and are not intended to represent every possible embodiment of the present invention.

Referring to the drawings, as best seen in Figures 1 through 9, the instrument body 11 has a proximal end 1 and a distal end 2. The distal end further includes a fixed portion (or fixed jaw) 3 and a movable portion (or moveable jaw) 4. The movable portion 4 is rotatable about pin 5 passing through the movable portion 4 and fixed portion 3 thereby forming a hinge.

The position of movable jaw 4 is determined by positioning rod 6 which transmits an opening or closing force to movable portion 4 via hinge pin 7. The position of positioning rod 6 is determined by the position of movable handle 8, which is connected to the proximal end of positioning rod 6 through pin 9. The positioning rod 6 passes through elongated section 18 of instrument body 11 and through passage 17.

Movable handle 8 is rotatably affixed to the instrument body 11 by pin 10 so that rotating movable handle 8 counterclockwise opens movable jaw 4 and rotating movable handle 8 clockwise closes movable jaw 4 with a closure force proportional to that applied between movable handle 8 and fixed handle 12. Closure pressure between the jaws may be maintained by a ratcheting action created through the interraction between tooth section 13 of movable handle 8 and serrations 14 on arcuate section 15 of fixed handle 12.

Closure pressure may be released by elastically deforming arcuate section 15 upward with pressure applied to proximal end 16 of the arcuate section. Fixed jaw 3 and movable jaw 4 may include serrations 8 formed on their angularly transposed surfaces to facilitate the grasping of tissue placed between them. Removable trocar 70 protrudes from the proximal end of instrument body 11.

As is best seen in Figures 11 through 13, one embodiment of the needle 20 has a proximal end 21 and a distal end 22, and a rectangular cross-section 27 with upper surface 28, lower surface 29 and lateral surfaces 30. The proximal end 21 includes a contoured proximal surface 23, conical in shape in one embodiment, and having a conical angle 24 and a conical axis 25 coaxial with needle centerline 26. The distal end 22 is shaped to form a cutting edge 28 having included angle 27. Suture 31 is connected to a needle lateral surface 30 at a distance 32 from the needle proximal end.

As is best seen in Figures 4, 5, 9, and 10, the instrument body 11 has a continuous passage 40 of varying cross-section extending from the proximal-most face 41 of instrument body 11 to the upper surface 42 of fixed jaw 3 near the jaw's distal tip. In section 43, extending a distance 44 from proximal face 41, the passage has a cylindrical cross-section of a specified diameter 56 as shown in Figures 7 and 8. In section 45, extending a distance 46 from the distal end of section 43, the passage is a rectangular channel 44, the height of the

channel 51 being slightly greater than the thickness 45 of needle 20. Distance 46 is sufficiently longer than the length of needle 20 to allow easy placement of the needle in the slot.

Section 47 of the slot extends from the distal end of section 45 to the termination of the slot at the top surface 42 of fixed jaw 3 and beneficially includes of a linear portion 48 and a radial portion 49 having a known radius 50. As is best seen in Figure 5, the cross-section of channel 40 in section 47 is rectangular having a height 51 slightly greater than the thickness 45 of needle 20 and a width 52 slightly greater than width 53 of needle 20. A slot 54 having a height 55 less than height 51 of passage 40 extends through the entirety of section 47.

As is best seen in Figures 14 through 17, upper jaw 4 contains a shaped passageway 60 having a width 61 slightly larger than width 52 of passage 40 and extending from the jaw's lower surface 63 to upper surface 64. As best seen in Figures 4 and 10, upper jaw 4 protrudes distally a distance 62 beyond lower jaw 3.

Referring to Figures 18 through 22, the force-supplying mechanism is a trocar 70 that is an assembly including a stepped cylindrical rod 71 and hub 72 and having a distal end 73 and proximal end 74, with the hub being attached to proximal end 74. Stepped metallic cylindrical rod 71 features a larger diameter section 75 of specified length 76 and diameter 77, with the diameter being slightly smaller than diameter 56 of section 43 of passage 40 so allowing trocar 70 may move freely within instrument body 11 when inserted into passage 40. Cylindrical rod 71 has a smaller diameter section 78 of specified length 79 and diameter 80, with the diameter being slightly smaller than height 51 of sections 45 and 47 of passage 40 allowing trocar 70 to move freely within elongated section 18 of instrument body 11 when inserted into passage 40. Rod 71 is hardened throughout its length to prevent bending, except section 81 extending a length 82 from distal tip 73 is annealed for high malleability. Distal tip 73 is formed to a conical shape of conical angle 83, with the conical angle being equal to conical angle 24 on proximal end 21 of needle 20.

Referring to Figures 23 and 24, when prepared for use, needle 20 is inserted laterally into section 45 of passage 40 with the lateral surface 30 with suture 31 facing the open side

of channel 40 and suture 31 extending from elongated section 18 of body 11. After insertion, needle 20 is moved distally to section 47 of channel 40; trocar 70 is inserted into channel 40 of instrument body 11, and positioned as shown in Figures 23 and 24.

Referring to Figures 25 and 26, when using the instrument to pass a suture the movable jaw 4 is opened using movable handle 8. Trocar 70 is inserted into instrument body 11 until trocar distal end 73 engages needle proximal end 21. Suture 31 carried by the needle 20 moves freely in slot 54.

During use of the device, as seen best in Figures 27 and 28, tissue is grasped between upper jaw 4 and lower jaw 3. Referring to Figures 29 and 30, advancing trocar 70 a distance 85 distally causes needle 20 to move distally in channel 20, the distal portion of the needle being formed to a radius 50 by the radial portion 49 of passage 40.

Referring to Figures 31 and 32, advancing the trocar an additional distance 86 causes needle 20 to be formed to a radial shape of radius 87, radius 87 being larger than radius 50 of section 49 of passage 40 due to spring back of the needle after leaving the passage radial section 49. Needle 20 follows a radial path through the tissue. Advancing trocar 70 an additional distance 88 (see Figures 33 and 34) causes needle 20 to advance along its radial path until needle distal tip protrudes above top surface 64 of movable jaw 4, having passed through jaw 4 via passage 60.

As is best seen in Figures 35 and 36, advancing trocar 70 distally until hub 72 contacts distal face 41 of instrument body 11 advances needle 20 further through the tissue, with distal tip 73 of trocar 70 assuming a radial shape of radius 87 as it passes through radial portion 49 of passage 40. Alignment between trocar distal tip 73 and needle proximal end 21 is maintained by engagement of the needle proximal end conical recess with the with the trocar distal tip conical protrusion, needle proximal end conical radius 24 and trocar distal tip conical radius 83 being equal. In this manner, needle 20 and suture 31 are advanced a distance 89 into the tissue beyond the top surface of lower jaw 3.

As is best seen in Figures 37 and 38, withdrawing trocar 70 a distance 90 causes the trocar distal tip 73 to be withdrawn from the tissue into the distal portion of passage 40, leaving needle 20 and suture 31 in the tissue, with needle distal tip 22 protruding well above

the top surface of upper jaw 3. As seen in Figures 39 and 40, upper jaw 3 is now retracted with needle 20 moving freely within passage 60. Referring now to Figures 41 and 42, withdrawing the instrument axially causes needle 20 in slot 60 of upper jaw 3 to be pulled free from the tissue with suture 31 now passing through the tissue. Referring to Figures 43 and 44, closing jaw 3 causes it to grasp needle 20 thereby allowing further retraction of the needle and the suture. As seen in Figures 45 and 46, jaws 3 and 4 may be opened thereby freeing needle 20, and the needle rotated 90 degrees and re-grasped by jaws 3 and 4.

Although the above description references "needle 20," various other needle designs are equally applicable to the invention. In another embodiment, shown in Figures 47 through 49, needle 92 has a cross-section with two parallel sides, the lateral faces having a nearly radial profile, a shape producible by coining a cylindrical needle. Additionally, prior to delivery of the suture material, the suture material may be a standard suture or may be a smaller suture. As shown in Figure 47a, the suture material may be looped back into the needle 92 such that when the needle 92 is delivered to the tissue, a loop of suture material is delivered that may then be used for other purposes, such as an eyelet for the transfer of other sutures.

In another embodiment, shown in Figures 50 through 52, needle 94 has a non-uniform cross-section, upper and lower surfaces 95 and 96 having a plurality of angled surface segments 98 of angle 95 each surface terminating in a radius 96 so as to form a series of notches useful in engaging corners of passage 60 in upper jaw 3 so as to aid in needle retraction during axial withdrawal of the instrument.

In addition to alternative needle designs, jaw construction is likewise variable in accordance with the invention. In another embodiment, best seen in Figures 53 through 56, upper jaw 100 is of similar construction to upper jaw 3 except that passage 60 has been replaced with slot 101. As is best seen in figures 57 through 59, the distal protrusion 62 of upper jaw 4 beyond lower jaw 3 is required to allow needle 20 to enter passage 60 throughout the range of positions of upper jaw 4. Figure 60 is a sectional view of upper and lower jaws with jaws opened 100 percent and the suture being pulled through the tissue.

A further alternate needle 201 is shown in Figures 61 through 63. As is best seen in Figure 62, the needle of thickness 220 has a distal end 202 and a proximal end 203, with the distal end formed to a wedge shape having included angle 204 so as to form a cutting edge 205. The proximal end 203 has a conical shape 206 formed therein and having an angle 207 equal to angle 83 on the distal tip of trocar 70 shown in Figures 18 through 22. As is best seen in plan view Figure 61, needle 201 has three sections distinguished by their width. Proximal section 208 and distal section 209 have a width 210, while medial section 211 has a width of 212 than width 211. Distal section 209 is not of constant width, but rather tapers to a width 213 at its distal tip. The transition from middle section 211 to proximal section 208 is a taper of length 214 and angle 215. Suture 216 is connected to lateral surface 217 of proximal section 208 a distance 218 from proximal end 203.

An alternate upper jaw to be used in conjunction with alternate needle 201 is shown in Figures 64 through 71. As is best seen in Figures 64, 66 and 68, upper jaw 110 is constructed like upper jaw 4 having a distal end 111 and a proximal end 112, except that upper jaw 110 has a distal end slot 113, the distal slot having a proximal portion 114 and a distal portion 120, and the portions being distinguished by their width. Proximal portion 114 has a length 125 and a width 115 which is slightly larger than width 210 of proximal section 208 and distal section 209 of needle 201 as shown in Figure 61. Distal portion 120 has a width of 121 which is slightly larger than width 212 of middle section 211 of needle 201 shown in Figure 61.

As is best seen when viewing jaw 110 laterally as in Figure 65, distal portion 111 of jaw 110 has a hooked portion 126 formed therein, the hooked portion having a radius 127 and a height 128, height 128 being somewhat larger than thickness 220 of needle 201 as seen in Figure 62. As is best seen in axial sectional view Figure 71, proximal portion 114 of slot 113 has a portion 130 of height 131 with parallel sides and a portion 132 of height 133 whose lateral facing sides are angled outward at angle 134 so that the bottom of the slot is wider than the top of the slot.

The functioning of alternate needle 201 and alternate jaw 110 is best seen in Figure 72 through 75. Functioning of the needle and jaw are as explained previously except,

referring to Figure 72, needle 201 being of a shorter length than that of needle 20 and trocar 170 being of a shorter length than trocar 70, when trocar 70 is fully inserted to the limit of its travel, the portion of needle 201 remaining within tissue 171 is greater than that remaining in the previously explained embodiments. The length 175 of the portion of needle 201 protruding beyond tissue 171 is sufficient to cause the distal end of medial portion 211 of needle 201 to extend above surface 172, needle 201 having passed through proximal portion 114 of slot 113, and, as shown in Figure 72 passed into distal portion 120 of slot 113 due to movement of the instrument proximally.

In this embodiment, needle 201 is prevented from disengagement from the distal portion 120 of slot 113 because the width 210 of needle distal portion 209 is greater than width 121 of slot distal portion 120. Needle 201 is able to move freely within slot 113 parallel to the axis of the slot as width 212 of needle medial portion 211 is less than width 121 of distal portion 209 of slot 113. Referring to Figure 73, withdrawing the instrument proximally causes needle 201 to move distally and pivot within distal portion 120 of slot 113 so as to engage with the hook segment 126 of jaw 110, thereby allowing needle 201 to be extracted from tissue 171, causing suture 216 to be pulled through the tissue. As is best seen in Figure 74, after needle 201 is free of tissue 171 upper jaw 110 may be closed and additional suture pulled through the tissue. As seen in Figure 75, jaw 110 may be closed totally thereby allowing needle 201 and suture 216 to be withdrawn through a cannula.

An alternate needle made of Nitinol and formed to a radial shape during manufacture is shown in Figures 76 through 78. Manufacture of needle 400 is accomplished in two steps, namely the cutting of the needle blank profile 401 from sheet material, and forming of the needle to a shape having radius 402, with radius 402 being equal to forming radius 50 of lower jaw 3 as shown in Figure 10. Needle 400 may be used in the same manner as previous embodiments as it will be constrained in a straightened state by channel 47 (Figure 9) prior to deployment. Needle capture and retrieval are accomplished in the same manner as needle 201 described previously and shown in Figures 72 through 75. Conversely, a Nitinol needle may be used having a linear shape, which is constrained into the radial shape as the needle passes through the radius of the lower jaw 3. Additionally, in other embodiments, a smaller

Nitinol needle, i.e. having a smaller diameter, may be used for creating a looped suture in the tissue wherein the smaller needle creates a loop in the suture material as it is delivered due to the reduced diameter of the needle.

An alternate needle 500 having multiple "barbs" displaced along its lateral surfaces is shown in Figures 79 through 81. The needle features a distal end 501 shaped to a cutting edge 506 having included angle 507, and a proximal end 502 having a convex conical shape 503 with conical angle 504. The conical angle is, in one embodiment, equal to distal tip angle 83 of trocar 70, shown in Figure 21. Suture 508 is attached to a lateral face 510 a distance 511 from distal end 502. Needle 500 has a width 507 and a number of pyramid-shaped "barbs" 512 displaced along lateral surfaces 510, the lateral distance 513 between barb tips being greater than width 507. The barb protrusions are pyramidal in shape having a length 514, width 515 and height 516, the distal edge 517 forming an angle 518 with the lateral surface 510.

Figures 82 through 86 show an alternate upper jaw for use with needle 500. Jaw 600 in constructed in the manner of jaw 4, except that jaw 600 includes a hollow structure of wall thickness 602 forming a capture space 601. The capture space 601 is defined by the walls of the jaw and by the inner surface 603 of the jaw lower wall 604. Jaw lower wall 604 has a slot 605 of width 606, width 606 being greater than width 507 of needle 500, but less than distance 513 between barb tips of needle 500. The lower section of slot 605 is tapered outward so as to aid needle 500 in entering slot 605.

Needle 500 and upper jaw 600 are used in the same manner as needle and jaw configurations previously disclosed; that is, needle 500 is formed to a radial shape by the instrument, passes through tissue confined by pressure from the upper and lower jaws, and enters the upper jaw where it is captured for retrieval. Needle 500 and jaw 600 vary in the method of capture. Distal tip 501 of needle 500 enters slot 605 of jaw 600, and via the slot enters space 601. Slot 605, being less in width than distance 513 between the needle barb tips, causes the barb tips to deform as they pass into space 601 via slot 605. Also, because wall thickness 602 is rather thin, jaw 600 will spread slightly so as to allow the barbs to pass.

Because the barb proximal surfaces are square rather than tapered, the needle is retained in the slot.

The embodiments described thus far included a pair of jaws, beneficially a fixed jaw and movable jaw, with the later being additionally responsible for any capture of a needle having been radially deformed and passed through tissue. Although the invention has been described in terms of a fixed jaw and a movable jaw, it will be apparent to those of skill in the art of mechanical design that versions of the invention wherein both jaws move are also anticipated, assuming appropriate interaction associated with needle curvature and any capture of the needle.

In addition, there are situations, and embodiments of this invention, where capture is performed not by a jaw coupled to the same instrument, but rather, through the use of an additional instrument. Reference to Figures 87-91, which illustrate a simpler suture punch according to the invention, which is similar to the embodiments described above, but does not include an upper jaw to hold tissue and/or retain a needle once formed. Nevertheless, the same type of malleable needle according to the invention having a suture/suture loop is inserted into these simpler devices, and pushed down the channel by a pusher, which acts as the force-supplying mechanism. Since the terminal action of the needle is the same as that used with the more sophisticated device as described herein, the shaft of the channel must be stiff enough to resist a perpendicular vector force required to push the needle through the tissue. One advantage of these alternative designs is that such instruments may be used to plicate the shoulder capsule from the inside arthroscopically. Figure 87 is a drawing of a jawless suture punch according to the invention, including a curved distal end 802, and a proximal end 804 including an insertion point 806. Figure 88 is a drawing of a pusher adapted for use with the jawless punch of Figure 87. The pusher includes a sharpened malleable/spring steel tip 812 coupled to a blunt 814 through an eyelet 816 to receive a thread or suture loop. In operation, the curved tip 802 is placed next to tissue to be sutured, and the sharp tip inserted into the insertion point 806. The sharp tip is then advanced with the pusher of Figure 88 through the tissue, allowing the suture to be pulled through the tissue as well.

Figure 89 is a drawing of a lower jaw of a suture punch or a jaw-less design according to the invention. According to this embodiment, a malleable needle is inserted into a loading slot 820 such that the tip of the needle is proximate to the distal end by a distance of 1/8 inch, or thereabouts. The instrument is inserted through cannula, upon which time the tissue is grasped and a flexible trocar is pushed down trocar channel 822. As the flexible tip of the trocar nears the needle slot 820, the bend in the channel directs the tip down the needle slot, engaging the proximal end of the needle. As the trocar is advanced further, the needle is pushed through the forming section of the lower jaw, resulting in a deformation similar if not identical to the other embodiments described herein. Figure 90 is a drawing of a particularized capsular plication suture punch for the shoulder according to the invention. Distance d indicates the portion of the capsule to be plicated, with the capsule surface being shown at 902. A malleable needle is inserted into the proximal end of the device, which penetrates into and out of the capsule, with the entire instrument remaining on one side of the surface 902. The depth of the penetration may be controlled for the curvature of the insertion channel, and the malleability characteristics of the needle. Figure 91 is a simplified drawing which shows the way in which three rigidly positioned points may be used to curve a needle into a selected radius according to the invention. Once the needle and suture passes through the capsule, a separate needle capture mechanism 910 may be used to pull the suture through, as described elsewhere herein.

Figure 92 is a drawing depicted in partial transparent form, illustrating a more sophisticated jawless punch according to one embodiment of the invention, including yet a further alternative needle including a distal tip configured for grasping with a separate instrument. The instrument depicted generally at 920 includes a body portion having a squeeze handle 922 coupled to a ratchet 924 which engages with barbs 926 on a pusher mechanism. The pusher mechanism extends through the barrel of the instrument down to the distal tip 930, which terminates in a curved portion 932, and includes a breach loading slot 934 to receive a needle 940 attached to suture 941 and including a distal tip 942 configured for grasping. Figure 93 is an oblique drawing of the device of Figure 92. Figure 94 is a close-up view drawing of the distal end 930 including curved tip 932, breach loading slot 934

and specialized needle 940 having a tip 942 configured for manual grasping, the needle 940 being attached at its proximal end to suture material 941. Figure 95 is a side-view drawing of the device of Figure 93 with the needle loaded in position; Figure 96 is a perspective-view drawing of the configuration shown in Figure 95. Figure 97 is a side-view drawing showing the trocar being advanced by pushing on the proximal end of the pusher rods. Figure 98 is a detail drawing showing the needle being pushed passed the breached loading position, with the suture material extending out from a slot, and with the needle in position just prior to deformation. Figure 99 is a drawing which shows the needle being deformed and pushed out the distal end, as handle 922 is compressed, causing the ratchet 924 to advance the barbs 926 on the pusher rod. Figure 100 is a drawing which shows the needle fully advanced, now free of the distal tip of the instrument. Figure 101 is a close-up, detail view of the needle emerging from the curved distal tip of the instrument.

As discussed above, with respect to the jawless embodiments of this invention, a separate instrument would generally be used to grasp the formed needle, having passed through tissue to be sutured. While conventionally available tools such as forceps, and the like, may be used for such purpose, particularly with respect to the specialized needle shown in Figure 94 and elsewhere herein, specialized needle grasping instruments may be provided, as shown in Figures 102-104. Figure 103A is a drawing which shows a grasping mechanism 1002 having a specially shaped set of jaws to capture the tip of certain needles described herein. In particular, the embodiments of Figures 102-104 are specially suited to grasp the tip of the needle best seen in Figure 94. Figure 102A shows the jaws open ready to grab the tip of the needle. Figure 102B shows the needle grasped, and Figure 102C shows how, even once grasped, the tip of the needle may rotate within the jaws. Figures 103A-103C are side views of the embodiments of Figure 102A-102C, and Figure 104 is a perspective view of the grasping mechanism in conjunction with the tip of the needle.

Yet a further embodiment, intended for applications such as the repair of torn meniscus, torn labrum, capsular reefing to the labrum and other applications, is described in the following text and Figures 105 through 109. This embodiment is different from the previous embodiments in that the distal end of the insertion instrument is configured so that

the needle exits the instrument in a direction that is axial to the instrument, wherein a normal to the distal-most surface is parallel to the axis of the instrument. The needle is formed to a somewhat larger radius so that when it is fully inserted the needle tip protrudes from the upper (or lower) surface of the tissue undergoing repair, the needle being formed, in one embodiment, less than 90 degrees. When the needle is fully inserted, the insertion instrument is removed leaving the needle and suture embedded in the tissue with its distal tip exposed.

The retrieval instrument distal end is somewhat like the upper jaw of certain previous embodiments in that it has a hook shape designed to allow the captured needle to pivot freely in the plane in which it is formed. A feature allows the tool to exert a force on a needle tip in the distal as well as the proximal direction. The retrieval instrument distal end is also slotted, the slot having a width slightly greater than that of the reduced width region of the needle, but less than the width of the needle distal tip.

In use, the wedge shaped distal end of the instrument is inserted so that the reduced region of the needle is engaged by the slot in the instrument. Moving the instrument distally causes the needle to be pulled further through the tissue. When the head is fully engaged in the slot the needle is pulled the rest of the way through the tissue by moving the instrument distally a distance sufficient to free the needle from the tissue and expose a short length of suture. The retrieval instrument is then moved proximally with the needle pivoting in the distal hook so that it may be withdrawn through the cannula. After the needle is freed from the tissue, the retrieval instrument may be rotated about its axis so that the needle pivots in a plane in which there is sufficient space for this to occur.

Referring to the drawings, as best seen in Figures 105A through 105C, needle 2001 of width W_1 (2004) and height H_1 (2005) has a distal end 2002 and a proximal end 2003. A middle region 2009 having a width W_2 (2006) forms "shoulders" 2012 at its distal end 2002 which is sharpened. A suture 2007 is attached to lateral surface 2008 a distance L_1 (2010) from distal-most surface 2011.

Referring to Figure 106, retrieval instrument 2020 has a proximal portion 2021 formed to a handle shape and an elongated distal portion 2022 terminating in distal tip 2023.

Referring to Figures 107A through 107C, distal tip 2023 has a slot 2024 of width W_3 (2025) which is slightly larger than width W_2 (2006 in Figure 105A) but less than W_1 (2004). The profile of distal end 2023 has a distal surface 2026 inclined at an angle A_1 (2027) and a capture region 2028 bounded on its distal end by hook-shaped surface 2029 and on its proximal end by lateral surface 2030 displaced from surface 2029 a distance L_2 (2031) and surface 2032.

Figure 108 shows the distal portion 2040 of an insertion instrument of this embodiment. Needle 2001 is positioned in the forming channel 2047 and suture 2007 is affixed to the needle. Distal portion 2040 has two radii, R_1 (2041) and R_2 (2042) which together displace forming channel 2045 a distance D_1 (2046). Radius R_2 (2042) forms the needle to a radial shape having a radius R_3 (2049 in Figure 109C) slightly larger than R_2 (2042). A normal to distal-most surface 2048 is coaxial with the axis of the axis of portion 2040.

Referring to Figure 109A, tissue 43 is to be sutured to tissue 2044. In Figure 109B, the "tear" is closed by applying force to tissue 2043 using distal portion 2040. In Figure 109C, needle 2001 has been inserted in the same manner as in the previous embodiment. In Figure 109D, the insertion instrument has been removed and needle 2001 remains in place with suture 2007. In Figure 109E, retrieval instrument 2020 has been brought into position. Figure 109F, distal tip 2023 has been inserted such that needle 2001 is engaged in slot 2024 and surface 2026 (see Fig. 107B) acting on shoulders 2012 (Figure 105A) of needle 2001 has displaced the needle distally in tissue 2043 and 2044.

Referring to Figure 109G, distal end 2002 of needle 2001 is captured in region 20028 (Figure 107B). Displacing retrieval instrument 2020 distally (Figure 109H) causes needle 2001 to be extracted from tissue 2043 thereby pulling suture 2007 through the tissue. In Figure 109I additional suture has been pulled through the tissue. In Figure 109J, retrieval instrument 2020 has been moved proximally causing needle 2001 to pivot in distal tip 2023 . In Figure 109K, needle 2001 has pivoted into position for retrieval through a cannula.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings and examples, it is to be understood that

the disclosure is not limited to those precise embodiments, and various other changes and modifications may be affected therein by one skilled in the art without departing from the scope of spirit of the disclosure. All such changes and modifications are intended to be included within the scope of the disclosure as defined by the appended claims.